DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 16, 2014

PDG Product Design Group, Inc.
c/o Edward Kroll, President
Spectre Solutions, Inc.
5905 Fawn Lane
Cleveland, OH 44141

Re: K140023
Trade/Device Name: Elevation Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 16, 2014
Received: September 19, 2014

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at the following internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140023

Device Name
Elevation Manual Wheelchair

Indications for Use *(Describe)*
The Elevation Manual Wheelchair is intended to provide mobility to persons limited to a seated position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.10.16 20:09:22 -04'00'

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"510(k) SUMMARY"

AS REQUIRED BY SECTION 807.92(c)

(Modified October 06, 2014)

510(k) Owner's Name, Address, Telephone Number, Fax Number, Contact Person and Date Prepared.

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5905 Fawn Lane
Cleveland, Ohio 44141
Phone: (440) 546-9801
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Date Prepared: December 26, 2013

Name of Device

- Trade Name: Elevation Manual Wheelchair
- Common Name: Manual Wheelchair
- Classification Name: Wheelchair, Mechanical Product Code IOR

Predicate Device

The Elevation Manual Wheelchair is substantially equivalent to the Icon Wheelchairs ICON Adult Manual Wheelchair (K110985)

Device Description:

The PDG Product Design Group, Inc. Elevation Manual Wheelchair (Elevation) is a manually operated, user propelled, manual, mechanical wheelchair. Its intended function and use is to provide mobility to persons ages 12 and up (adolescents and adults) limited to a seated position. It is an ultra-light, rigid (non-folding frame) type wheelchair.

The device consists primarily of a lower frame assembly, a seat sling, a back rest and back upholstery, large rear wheels with hand rims for self-propelling the chair and front swivel type pivoting casters for turning.

The Elevation also has seat height and back rest recline angle adjustment capability that allow the user to self-adjust either the seat to floor height or the back rest recline angle while seated in the wheelchair. The Elevation is capable of up to 5 inches of rear to front seat height difference.

Device Function

Device function is dependent solely upon the wheelchair user. It does not function on its' own in any manner. The wheelchair user controls motion, speed and direction by propelling themselves using the hand rims located on the rear wheels.

Scientific Concepts

There are no complex scientific concepts related to the Elevation manual wheelchair. The Elevation is a simple, basic, manually operated mobility device.

Significant Physical and Performance Characteristics

Design:

The Elevation allows the user to adjust the seat height and back rest angle while the wheelchair is occupied. Seat height and back rest angle adjustment are achieved using gas springs which are mounted to the upper and lower frame assemblies. A tilt activator lever located on the right side of the lower frame is used to open and close the gas springs, thus activating and de-activating the adjustment features. It is to be used by adults and adolescents ages 12 and up with a maximum weight limit of 250lbs (114kg).

Materials:

The Elevation frame is made from round, mechanical aluminum tubing that is welded together. The upholstery is made from foam polyurethane padding with nylon cover. These materials conform to FDA recognized standard ISO 7176-16:2012.

Physical Properties:

The device consists primarily of a lower frame assembly, a seat sling, a back rest and back upholstery, large rear wheels with hand rims for self-propelling the chair and front swivel type pivoting casters for turning.

Intended Use/Indications for Use

The Elevation Manual Wheelchair is intended to provide mobility to persons limited to a seated position.

Predicate Device Comparison

The Elevation Manual Wheelchair is substantially equivalent to the Icon Wheelchairs ICON Adult Manual Wheelchair (K110985)

Performance Data: (Non-clinical Testing)

The Elevation Manual Wheelchair has been tested to the following standards;

- ISO 7176-1:1999 Determination of Static Stability
- ISO 7176-3:2003 Determination of Effectiveness of Brakes
- ISO 7176-5:2008 Determination of Overall Dimensions, Mass and Maneuvering Space
- ISO 7176-7:1998 Determination of Seating and Wheel Dimensions
- ISO-7176-8:1998 Requirements and Test Method for Static Impact and Fatigue Strength
- ISO 7176-13:1989 Determination of Coefficient of Friction of Test Surfaces
- ISO 7176-15:1996 Requirements for Information Disclosure, Documentation and Labeling
- ISO 7176-16:2012 Resistance to ignition of upholstered parts Requirements and test methods
- ISO 7176-22:2000 Set up Procedures

Conclusions of non-clinical tests

The results of the non-clinical tests confirm that Elevation Manual Wheelchair is substantially equivalent to the predicate device.

Elevation Manual Wheelchair Comparative Analysis

ITEM/SPECIFICATION	ICON Adult Manual Wheelchair	PDG PRODUCT DESIGN GROUP ELEVATION	DISCUSSION
510(k) Accession Number	K110985	K140023	N/A
Clearance Date	May 3, 2011	TBD	N/A
Indications for Use	Provide mobility to persons limited to a seated position	Same	No difference
DIMENSIONS, WEIGHT AND WEIGHT LIMITATION			
Front Seat to Floor Height	12”-21”	19 1/2”-20 1/2”	While the ICON has a wider range it includes seat to floor heights which are the same as the Elevation.
Caster Size	3”-6”	4”x1”, 4”x 1.5” or 5”x 1.5”	The predicate offers 3” and 6” diameter casters and the Elevation does not. However, the Elevation caster sizes are within the range of the predicate
Rear Wheel Diameters	24”-25”	24”, 25” and 26”	The Elevation offers a 26” diameter wheel and the ICON does not. However, the remaining rear wheel sizes are the same. This difference is not significant in terms of safety or effectiveness. The 26” rear wheel would make the Elevation slightly easier to self-propel.
Seat Width	12”-19”	14”-18”	The predicate offers a wider range than the Elevation however, the Elevation seat widths are within the range of the predicate.
Seat Depth	12”-20”	14”-18”	The predicate offers a wider range than the Elevation however, the Elevation seat depths are within the range of the predicate.
User Weight Limit	250 lbs.	Same	No difference

ITEM/SPECIFICATION	ICON Adult Manual Wheelchair	PDG PRODUCT DESIGN GROUP ELEVATION	DISCUSSION
Chair Weight	23 lbs.	25 lbs. including wheels	The Elevation is slightly heavier than the ICON. This is likely due to the gas springs which are used for the seat and back angle adjustment features of the Elevation. The 2 pound difference is not significant and has no effect on safety or effectiveness.
MATERIALS			
Frame Material	Aluminum, Titanium and Composite	Aluminum	No difference since both are made from aluminum
Upholstery	Polyurethane Foam with Nylon Cover	Same	No Difference
Hand Rims	Aluminum Tubing	Same	No Difference
FEATURES:			
Ultra-Light Frame	Yes	Yes	No Difference
Back Angle Adjustment	Yes but must be done without user seated in the wheelchair.	Yes but can be adjusted with the user in the wheelchair.	Both devices have back angle adjustment capability and the fixed angles for the predicate are within the range of the Elevation. Adjusting the back angle with the chair being occupied has no effect on safety. The gas springs move the back rest angle slowly. A failure of the gas spring while fully extended would only return the back rest to its' lower most position in a slow manner. A failure in the fully retracted position would only result in the back rest feature not functioning. In either case, patient safety is not compromised.
Elevating Seat	No	Yes. Seat may be raised and lowered while the user is seated in the wheelchair.	Adjusting the seat height with the user in the chair has no effect on safety. The gas springs raise and lower the seat slowly. While a raised seat does make the chair more susceptible to tipping, the Elevation passed the ISO 7176- 1 Static Stability test with the elevated seat in its' highest position. Gas spring failure in the retracted position would result only in the elevating seat feature becoming nonfunctional. Failure of one spring in a fully extended position has no effect as one spring has sufficient force to ensure the seat is lowered in a slow and non-abrupt manner.
Full Frame Design	Yes	No. Frame is in two pieces mounted with gas springs for Elevating Seat Function.	Two piece frame has no effect on device safety. Frame strength is not compromised.